

08-12-02

213.1077-CTML-U



**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: Unknown

Art Unit: 1614

Re: Application of:

CHOE, Y.H., et al.

Serial No.:

10/078,649

Filed:

February 19, 2002

For:

**TERMINALLY-BRANCHED POLYMERIC  
LINKERS AND POLYMERIC  
CONJUGATES CONTAINING THE SAME**

RECEIVED  
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**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner  
for Patents  
Washington, D.C. 20231

August 8, 2002

Sir:

Pursuant to M.P.E.P. §609 and 37 C.F.R. §§1.56, 1.97-1.99, Applicants herewith submit form PTO-1449 (7 sheets) which lists references cited in the International Search Report (ISR) dated June 18, 2002 for the present application and of which Applicants are aware. A copy of the ISR is also enclosed herewith. The Examiner is also alerted to the fact that the following related patent applications are currently pending in the United States Patent and Trademark Office: United States Patent Application Serial Nos. 10/067,930, 09/852,335, 09/758,993 and 10/078,730.

This submission does not represent that a search has been made or that no better art exists. While the term "references" is used in citing the U.S. patents called to the Examiner's attention herein, Applicants do not make any admission that each or all of them are "prior art" references within the meaning of the statutory and case law.

Applicants reserve the right to contend, where appropriate, that a patent asserted against any claim of the present application is not prior art under the facts and the law.

Applicants also reserve the right to present appropriate arguments and/or evidence to establish patentability over the references, should one or more of the references be applied against the claims of the present application.

Applicants request that the Examiner independently determine those items which the Examiner would consider the most pertinent of all the references cited herein.

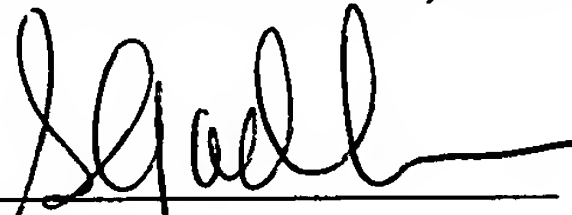
This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits. Accordingly, this document complies with the requirements of 37 C.F.R. §1.97(b).

No fee is believed to be due. Any deficiency or overpayment concerning this document should be charged or credited to Deposit Account No. 50-0217. A duplicate copy of this sheet is enclosed.

It is respectfully requested that the references cited in the accompanying PTO-1449 Form be considered and made of record.

Respectfully submitted,

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I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to "Assistant Commissioner of Patents, Washington, D.C. 20231" on August 8, 2002.  
ROBERTS & MERCANTI, L.L.P.

BY: \_\_\_\_\_

  
Sapna Gadhia

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. <b>213.1077-CTML-U</b>	SERIAL NO. <b>10/078,649</b>
	Choe, Y. H., et al.	
	FILING <b>02/19/2002</b>	GROUP <b>1614</b>

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	5,965,119	10/12/99	Greenwald, et al.		12/30/97
	A2	5,130,126	07/14/92	Koyama, et al.		03/28/91
	A3	5,994,517	11/30/99	Ts'o, et al.		11/22/96
	A4	6,039,931	03/21/00	Schmitt-Willich, et al.		10/06/94
	A5	6,020,373	02/01/00	Schellenberg, et al.		04/21/97
	A6	5,885,548	03/23/99	Maier, et al.		11/30/95
	A7	5,756,825	05/26/98	Safavy, et al.		04/16/93
	A8	4,943,579	07/24/90	Vishnuvajjala, et al.		10/06/87
	A9	5,283,339	02/01/94	Arnold, et al.		08/05/92
	A10	5,433,886	07/18/95	Sherbondy, et al.		05/07/92
	A11	5,643,575	07/01/97	Martinez, et al.		10/27/93

**FOREIGN PATENT DOCUMENTS**

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO
A12	WO 99/45964	09/16/99	PCT			
A13	WO 96/23794	08/08/96	PCT			
A14	WO 81/01145	04/30/81	PCT			
A15	WO 93/24476	12/09/93	PCT			
A16	WO 95/10304	04/20/95	PCT			

**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	A17	Guiotto, Andrea, et al., An Improved Procedure for the Synthesis of Branched Polyethylene Glycols (PEGs) with the Reporter Dipeptide Met-Beta-Ala for Protein Conjugation, Bioorganic & Medicinal Chemistry Letters, volume 12, pgs. 177-180 (2002).
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	A19	5,646,159	07/08/97	Wall, et al.		07/20/94
	A20	5,679,852	10/21/97	Platzek, et al.		06/02/95
	A21	5,583,206	12/10/96	Snow, et al.		11/28/94
	A22	5,693,310	12/02/97	Gries, et al.		11/19/90
	A23	5,454,954	10/03/95	Alfano, et al.		11/02/94
	A24	5,569,720	10/29/96	Mongelli, et al.		07/27/95
	A25	5,547,981	08/20/96	Greenwald, et al.		02/17/94
	A26	5,622,986	04/22/97	Greenwald, et al.		10/19/94
	A27	4,179,337	12/18/79	Davis, et al.		07/28/77
	A28	5,183,660	02/02/93	Ikeda, et al.		08/15/91
	A29	5,489,589	02/06/96	Wittman, et al.		12/07/94

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					YES	NO
A30	WO 98/13059	04/02/98	PCT			
A31	WO 01/09139 A1	02/08/01	PCT			
A32	WO 96/22277	07/25/96	PCT			
A33	WO 99/30727	06/24/99	PCT			

**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		A34	Twyman, L.J., et al., The Synthesis of Water Soluble Dendrimers, and their Application as Possible Drug Delivery Systems, Tetrahedron Letters, Volume 40, p. 1743-46 (1999).
		A35	Greenwald, R.B., Review Oncologic, Endocrine & Metabolic Drug Delivery Systems: anticancer prodrugs and their polymeric conjugates. Exp. Opin. Ther. Patents (1997) 7(6): 601-609

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	A36	5,498,729	03/12/96	Domb			02/22/93
	A37	5,614,549	03/25/97	Greenwald, et al.			01/30/95
	A38	5,672,584	09/30/97	Borchardt, et al.			04/25/95
	A39	6,113,906	09/05/00	Greenwald, et al.			12/29/98
	A40	5,605,976	02/25/97	Martinez, et al.			05/15/95
	A41	5,561,119	10/01/96	Jacquesy, et al.			04/29/92
	A42	5,349,001	09/20/94	Greenwald, et al.			01/19/93
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	A44	5,122,614	06/16/92	Zalipsky			04/19/90
	A45	5,093,531	03/03/92	Sano, et al.			05/05/89
	A46	4,179,337	12/18/79	Davis, et al.			07/28/77
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<b>OTHER DOCUMENTS</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
		A47	Cerny, L. C., et al., A Potential Blood Substituted from A Tetronic Polyol And A Modified Hemoglobin, Art. Cells & Immob. Biotech., 20(1), 71-93 (1992)				
		A48	Ohya, Y., et al., Synthesis and Cytotoxic Activity of Conjugates of Monomethoxy-Poly-(ethylene glycol) End- Capped with Doxorubicin via Ester, Amide, or Schiff's Base Bond, Journal of Bioactive and Compatible Polymers Vol. 10 Jan., 1995, 51-66				
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	A49	5,112,739	05/12/92	Meneghini, et al.			08/02/88
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	A51	5,382,657	01/17/95	Karasiewicz, et al.			08/26/92
	A52	5,614,549	03/25/97	Greenwald, et al.			01/30/95
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OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>			
		A55	Shearwater Polymers, Inc., Catalog Polyethylene Glycol Derivatives, 1997-1998
		A56	Williams, Matthew A., and Henry Rapoport, Synthesis of Enantiomerically Pure Diethylenetriaminepentaacetic Acid Analogues, J. Org. Chem. 1193, 58, 1151-1158

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*EXAMINER INITIAL	OTHER DOCUMENTS	<i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
A57		Zalipsky, S., C. Gilon and A. Zilkha, Attachment of Drugs to Polyethylene Glycols, <i>Eur. Polym. J.</i> , Vol. 19, No. 12, pp. 1177-1183, 1983
A58		Shearwater Polymers, Inc., Quarterly Newsletter, March 1998
A59		Ouchi, T., et al., Synthesis and Antitumor Activity of Poly(Ethylene Glycol)s Linked to 5-Fluorouracil via a Urethane or Urea Bond. <i>Drug Design &amp; Discovery</i> , 1992, Vol. 9, pp. 93-105
A60		Greenwald, Richard B., et al., Drug Delivery Systems Employing 1,4-or 1,6-Elimination: Poly(ethylene-glycol) Prodrugs of Amine-Containing Compounds, <i>Journal of Medicinal Chemistry</i> , Volume 42, Number 18, pages 3657-3667, 1999
A61		Maeda H., et al., Tumor vascular permeability and the EPR effect in macromolecular therapeutics: a review, <i>Jour. of Controlled Release</i> 65 (2000) pages 271-284
A62		Greenwald, Richard B., et al., Drug Delivery Systems Based on Trimethyl Lock Lactonization: Poly(ethylene glycol) Prodrug of Amino-Containing Compounds, <i>Journal of Medicinal Chemistry</i> , Volume 43, Number 3, pages 475-487 (2000)
A63		de Bont, Dries B.A., et al., Synthesis and Biological Activity of B-Glucuronyl Carbamate-Based Prodrugs of Paclitaxel as Potential Candidates for ADEPT, <i>Bioorganic &amp; Medicinal Chemistry</i> , Volume 5, Number 2, pages 405-414 (1997)
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A66		Leenders, R.G.G., et al., B-Gucuronyl Carbamate Based Pro-moieties Designed for Prodrugs in ADEPT, <i>Tetrahedron Letters</i> Vol. 36, No. 10 pp. 1701-1704 (1995)
A67		Waldmann, H., et al., Synthesis of the Palmitoylated and Farnesylated C-Terminal Lipohexapeptide of the Human N-Ras Protein by Employing an Enzymatically Removable Urethane Protecting Group, <i>Angew. Chem Int. Ed.</i> 1995, 34, No.20, pp. 2259-2262
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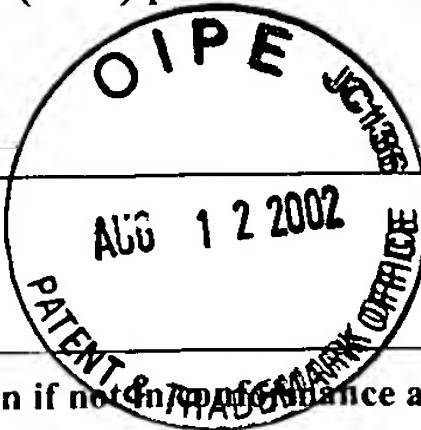
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	A70	Wakselman, M. et al., An Alkali-labile Substituted Benzyloxycarbonyl Amino-protecting Group, JCS Chem. Comm. pp. 593-594 (1973)
	A71	Cari, P.L., et al., A Novel Connector Linkage Applicable in Prodrug Design, J. Med. Chem., Vol. 24, No. 5, 479-480 (1981)
	A72	Wang, B., et al., Synthesis of a Novel Esterase-Sensitive Cyclic Prodrug System for Peptides That Utilizes a "Trimethyl Lock" Facilitated Lactonization Reaction, J. Org. Chem (1997), 62, 1363-67
	A73	Amsberry, K.L. et al., The Lactonization of 2'-Hydroxyhydrocinnamic Acid Amides: A Potential Prodrug for Amines, J. Org. Chem. Vol. 54, No. 23, pp. 5867-5877 (1998)
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	A77	Amsberry, K., et al., Amine Prodrugs which Utilize Hydroxy Amide Lactonization. I.A. potential Esterase-Sensitive Amide Prodrug Pharmaceutical Research Vol. 8, No. 4, 1991
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	A79	Brana, Miguel, et al., Synthesis of Antitumor Dendritic Imides, Bioorganic & Medicinal Letters 11 (2001) Pgs. 3027-3029
	A80	Bogdanov, et al. Long-Circulating Blood Pool Imaging Agents, Advanced Drug Delivery Reviews 16 (1995) p. 335-348

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	A81	Hermentin, et al., Attachemnt of Rhodosaminylanthracyclinone-Type Anthracyclines to the Hinge Region of Monoclonal Antibodies, Bioconjugate Chem., Vol. 1, No. 2, p. 100-107 (1990)
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	A84	Hines, Jennifer V., et al., Paramagnetic Oligonucleotides: Contrast Agents for Magnetic Resonance Imaging with Proton Relaxation Enhancement Effects. ,Bioconjugate Chem., Vol. 10, No. 2, 1999, pp 155-158.
	A85	Chen, Jiyan., Thiol-Reactive Luminescent Chelates of Terbium and Europium, Bioconjugate Chem. 1999, 10, 311-315.
	A86	King, Dalton H., et al., Monoclonal Antibody Conjugates of Doxorubicin Prepared with Branched Linkers: A Novel Method for Increasing the Potency of Doxorubicin Immunoconjugates., Bioconjugate Chem., Vol. 10, pp 279-288 (1999)
	A87	Greenwald, R.B., et al., Highly Water Soluble Taxol Derivatives 2'-Polyethleneglycol Esters As Potential Prodrugs, Bioorganic & Medicinal Chemistry Letters, Vol 4. No. 20, pp. 2465-2470 (1999)
	A88	Ueda, Y., et al., Synthesis and Antiumor Evaluation of 2'-Oxcarbonylpaclitaxels (Paclitaxel-2'-Carbonates) Bioorganic & Medicinal Chemistry Letters, Vol. 4, No. 15,. pp. 1861-1864 (1994)
	A89	Greenwald, et al., Drug Delivery Systems based on Trimethyl Lock Lactonization: Poly(ethylene glycol) Prodrugs of amino-containing compounds; 2000, Chem. Abstract 132: 227266
	A90	Greenwald, et al., Trialkyl-Lock-Facilitated Polymeric Prodrugs of Amino-containing Bioactive Agents; 1999, Chem. Abstract 131: 92540

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